K040231

JUL 1 3 2004

510(k) SUMMARY

Submitted by:

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Device Name:

Common Name: Punctal Plug
Proprietary Name: InteliPORT® Occluding Device

Device Classification:

Lacrimal system plugs have not been officially classified, but have been historically regulated through the 510(k) process.

Indication

The InteliPORT® Occluding Device is intended for use in patients experiencing dry eye symptoms such as redness, burning, reflex tearing, itching or foreign body sensations which can be relieved by occluding the lacrimal drainage system in order to increase tear volume.

The InteliPORT® Occluding Device may be used in the treatment of dry eye syndrome and the dry eye components of various ocular surface diseases.

Other patients that may benefit are: patients with arthritis, patients taking systemic or topical medications known to produce dry eyes, contact wearers who experience dry eye related problems, and patients who live in dry climates, or spend extended periods of time in low humidity environments (such as air conditioning).Topical eye drops may be more effective with punctal occlusion because tear drainage will be retarded, and tear breakup time extended.

Description:

The InteliPORT® Occluding Device is designed to deliver a custom fit plug through the punctal opening to block tear drainage. The self-forming plug (Intelimer Occluding Material*) is heated and inserted through the punctal opening into the proximal canaliculus as a melted viscous liquid. It rapidly solidifies to conform to the shape of the ampulla and canaliculus. The InteliPORT® Occluding Device is composed of a transitional and continuous block of Intelimer Occluding Material (matrix) which is adequate for delivering two doses in a single patient use applicator and is provided in a sealed, sterilized

package. The Intelimer Occluding Material is liquefied in the applicator by warming it a few degrees above body temperature via an internal 1.5 volt battery and a heating coil. The narrow applicator tip is then inserted into the punctal opening and the plunger is pushed to deliver the Intelimer Occluding Material. Once inside the duct, the material cools to form a customized plug that conforms to the shape of the individual's ampulla and canaliculus. The volume of material delivered, approximately 4-7 micro liters, is controlled so as to flow into the common ampulla and canaliculus. Restoration of patency may be accomplished by irrigation with warm sterile saline.

Substantial Equivalence Comparison:

The InteliPORT® Occluding Device is substantially equivalent to the OASIS Medical Soft Plug® Silicone Punctal Plug (K980437).

Safety and Effectiveness:

A. Non-Clinical Data

Comprehensive studies have been conducted to evaluate the safety of the InteliPORT® Occluding Device. In summary, based on the preclinical safety evaluations performed or sponsored by Alcon Research, Ltd., Alcon concludes:

1. The InteliPORT® Occluding Device was determined to have no dermal or systemic toxicity and no sensitization potential when the polymer alone, Intelimer Occluding Material or extracts of these materials were evaluated.

2. The InteliPORT® Occluding Device was determined to be non-cytotoxic, non-hemolytic and non-pyrogenic in a series of tests with the Intelimer Occluding Material or extracts of the Intelimer Occluding Material.

3. Extracts of the Intelimer Occluding Material were determined to be non-mutagenic in the Ames Salmonella mutagenicity assay and in the chromosomal aberration assay with human peripheral lymphocytes.

4. The plastic applicator was determined in standard USP plastics testing not to present a hazard to the user.

5. The InteliPORT® Occluding Device was determined to be safe and compatible with static magnetic resonance fields up to 1.5 Tesla, therefore, the InteliPORT® Occluding Device does not present a safety hazard to the patient undergoing MR imaging and the device should not interfere with the quality of the MR image.

6. The InteliPORT® Occluding Device was determined to have no unacceptable or marginal histological effects at 75°C, the highest temperature evaluated. These studies were based on gross and histological evaluation of the punctal and periocular tissues following implantation of the device over a range of temperatures. Therefore, the

specification for maximum temperature of 70°C is not considered to be a risk to the patient.

7. Removal techniques using administration of a mineral oil-based ophthalmic lubricant with or without warm saline (less than 50°C) and a warm compress were determined to have no adverse effects on the nasolacrimal duct. Use of warm saline alone, lubricant with warm saline, or lubricant with warm saline and a warm compress all restored duct patency for 100% of rabbits.

8. The chronic irritation of the InteliPORT® Occluding Device was evaluated in rabbits for 182 days, with interim evaluations at 7, 14, 28 and 91 days. The InteliPORT® Occluding Device was implanted into the right eyes of NZW rabbits (not Specific Pathogen Free) with either a Herrick plug or no plug in the left eye as controls. Rabbits were observed for signs of ocular irritation, and histopathology was conducted on the nasolacrimal ducts. Sporadic instances of minimal conjunctival redness were observed in both the left and right eyes of animals and were judged not to be indicative of ocular irritation. Out of 30 rabbits, two (Day 91 group) were noted to have discharge and conjunctivitis in the right eye. Standard veterinary care was administered and the conditions resolved. Bacterial cultures were obtained from the two rabbits and flora common to the rabbit were isolated. The study director noted that occlusion of the nasolacrimal duct allowed a sub clinical infection to develop into local clinical disease. Since no Herrick plugs were found at tissue dissection to verify their presence during the study, a valid comparison cannot be made to the lack of conjunctivitis in those eyes. Additionally, no signs were observed in rabbits implanted with plugs for 180 days, and the occurrences may have been sporadic in nature. Average histopathology scores were ≤ 3.5 for right (InteliPORT® Occluding Device) and left (control) eyes, and were judged to be acceptable. It was concluded that the InteliPORT® Occluding Device was not irritating to the nasolacrimal duct in rabbits.

Based on the results of these studies, the InteliPORT® Occluding Device is safe for its intended use in the reversible occlusion of the punctum for treatment of dry eye symptoms and should not present an ocular hazard to the consumer when used according to the directions for use.

B. Clinical Data

In a multicenter, randomized well-controlled clinical trial, InteliPORT® Occluding Device was implanted bilaterally for up to three months in 107 patients with a diagnosis of dry eye syndrome. Many subjects retained the plugs following the three-month study. The study results demonstrated reductions in the severity of dry eye symptoms, increased tear retention, increased tear break-up time and a reduction in corneal fluorescein staining. Canaliculitis was reported in 7 eyes either during (4 eyes) or after exiting (3 eyes) the study. The onset day occurred

from 38 to 392 days following plug insertion and the duration ranged from 4 to 12 days. All cases resolved with topical antibiotic therapy.

The InteliPORT® Occluding Device is safe and effective, when used according to the directions for use, for its intended use in the reversible occlusion of the punctum for treatment of dry eye symptoms.

*Intelimer is a trademark of Landec Corporation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 3 2004

Alcon, Inc.
c/o Kim B. Kracke
Alcon Research, LTD.
6201 South Freeway
Fort Worth, TX 76134-2099

Re: K040231
Trade/Device Name: InteliPORT ® Occluding Device
Regulation Name: Punctal Plug
Regulatory Class: Unclassified
Product Code: LZU
Dated: July 7, 2004
Received: July 9, 2004

Dear Ms. Kracke:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K040231

Device Name: InteliPORT® Occluding Device

Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Don Calogero

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

510(k) Number K040231

Prescription Use X OR Over-The-Counter Use (Per 21 CFR 801.109)